

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CYTYC CORPORATION,)	
)	
Plaintiff,)	Civil Action No. 03-11142 (DPW)
)	[Lead Case]
v.)	
)	
TRIPATH IMAGING, INC.,)	
)	
Defendant.)	
_____)	
TRIPATH IMAGING, INC.,)	
)	
Plaintiff,)	Civil Action No. 03-12630 (DPW)
)	
v.)	
)	
CYTYC CORPORATION,)	
)	
Defendant.)	
_____)	

**MEMORANDUM IN SUPPORT OF TRIPATH IMAGING, INC.'S
MOTION TO EXCLUDE DEFENSES BASED ON CYTYC'S CDS-1000**

I. INTRODUCTION

At approximately 11 p.m. on January 31, 2005, the last day of a fifteen-month fact discovery period in this case, Cytac disclosed for the first time in supplemental interrogatory responses an entirely new defense theory in this case: two of the four patents-in-suit, United States Patent Nos. 6,327,377 ("377 Patent") and 5,715,327 ("327 Patent"), are allegedly invalid in view of a Cytac product development project known as the CDS-1000. *See* Ex. 1, faxed copy of Plaintiff's Second Set of Objections and Supplemental Answers to Defendant's First Set of Interrogatories (Nos. 5 and 6). Cytac waited until after the close of fact discovery to disclose the claim that the CDS-1000 was alleged as invalidating prior art despite the fact that the CDS-1000 was a Cytac product developed

though never marketed during the late 1980s and early 1990s, and thus Cytyc, along with its legal team and technical advisors were certainly aware of this product from the outset of this case. As summarized below, there is also very compelling evidence that Cytyc was aware of this defense many months (if not much longer) before it was disclosed to TriPath after the close of fact discovery. It is inconceivable, particularly given the lengthy and thorough discovery process in this case, that Cytyc can expect to rely upon its own product as invalidating prior art when it never disclosed that product as prior art to TriPath during fact discovery.

Cytyc should have been aware of any invalidity arguments based on its own CDS-1000 device since it filed suit for declaratory judgment of patent invalidity on June 16, 2003. Nevertheless, Cytyc engaged in a litigation strategy to keep this information from TriPath until a point where TriPath could conduct no discovery on the issue. In fact, it is readily apparent that Cytyc has tried to “set up” TriPath with respect to this inevitable motion. In particular, Cytyc dumped many documents relating to the CDS-1000 on TriPath, including extremely lengthy and complex software code, as part of its production just three weeks before the close of fact discovery. At that time, Cytyc offered to postpone the deposition of Dr. Zahniser (head of development efforts on CDS-1000 project as well as head of development efforts on accused infringing ThinPrep Imaging System), purportedly to allow TriPath additional time to review the code. *See* Ex. 8, letter dated January 10, 2005. However, Cytyc failed to disclose *why* it was producing this information to TriPath, and therefore TriPath was unaware that it needed to examine the CDS-1000 as an alleged piece of prior art. Indeed, TriPath understood that the CDS-1000 documents produced on the eve of fact discovery’s close related to infringement issues because the CDS-1000 is the predecessor device to the Thin Prep Imaging System, the product accused of patent infringement. Declaration of Michael Ray at ¶¶ 1-9 (“Ray Decl.”); Declaration of Charles Burke at ¶¶ 1-7 (“Burke Decl.”). As a result,

because TriPath never knew that the CDS-1000 was being cited as prior art, TriPath never conducted any discovery to test this theory. *Id.*

Even though Cytyc was certainly aware of its alleged invalidity theory based on the CDS-1000 much earlier than its document production in January 2005, Cytyc purposely did not disclose this information to TriPath until approximately 11 p.m. on January 31 after all fact discovery was completed. Cytyc's conduct has severely prejudiced TriPath in that TriPath was unable to undertake the substantial amount of discovery that would be necessary on the legal and factual bases underlying Cytyc's new allegations of invalidity based on the CDS-1000. *See* Ray Decl., ¶¶ 4-8; Burke Decl., ¶4. Indeed, Cytyc's conduct has thwarted the very purposes of discovery under the Federal Rules, to prevent trial by surprise and ambush. Indeed, when the parties' roles were reversed earlier in this case (TriPath attempted to assert an infringement claim that it had not disclosed in fact discovery), Cytyc insisted that such conduct was improper and undisclosed claims had to be withdrawn. *See* Ex. 6, letters dated March 16 and 22, 2005. TriPath agreed and withdrew the undisclosed claim. *See id.*, letter dated March 23, 2005. The result should be the same here – any defense of patent invalidity or unenforceability based or upon the CDS-1000 should be excluded from this case.

II. PROCEDURAL AND FACTUAL BACKGROUND

A. The Parties' Claims

On June 16, 2003, Cytyc filed its complaint in the lead case of these consolidated proceedings. Cytyc's complaint asserted claims for declaratory judgment of invalidity and non-infringement of six TriPath patents. Cytyc's action was later consolidated with TriPath's patent infringement action filed in North Carolina, and Cytyc removed two patents from its claims by way of a Second Amended Complaint. TriPath asserts in its Second Amended Complaint and Counterclaim that Cytyc has willfully infringed the four patents-in-suit by making, using and selling

Cytec's ThinPrep Imaging System (a semi-automated, computer-assisted imaging system used for primary screening of Cytec's Pap test slides). Cytec asserts in its declaratory judgment pleadings – Second Amended Complaint and Counterclaim – that the four TriPath patents have not been infringed by Cytec and are invalid based on unidentified prior art.

B. The Lengthy Fact Discovery Period In This Case

The parties filed a Local Rule 16.1 Joint Statement on October 23, 2003. The Court entered a Scheduling Order on October 30, 2003. Pursuant to the original Scheduling Order, fact discovery ended on June 30, 2004, and expert discovery ended on October 15, 2004. On March 18, 2004, the Court granted the parties' Joint Motion to Amend Scheduling Order. The fact discovery period was then scheduled to end on August 31, 2004, with the expert discovery period ending on October 31, 2004. On October 14, 2004, the Court granted the parties' Joint Motion to Amend Order on Motion to Amend. The fact discovery period was then scheduled to end on January 31, 2005, and the expert discovery period would end on April 29, 2005.

The parties completed fact discovery in this case on January 31, 2005, except for a few inventor depositions taken by Cytec in February 2005. Accordingly, the parties engaged in an approximately 15-month fact discovery period in this case. Yet, as shown below, at no time during this period did Cytec allege that the CDS-1000 device was a basis for invalidity of any of the patents-in-suit. Expert discovery is still continuing in the case.

C. Cytac's Discovery Responses and Document Production In This Case

TriPath served a first set of interrogatories on Cytac on November 13, 2003. TriPath's Interrogatory Number 6 provides, "State the basis for Cytac's contention that the TriPath patents listed in the First Amended Complaint are invalid or unenforceable, including but not limited to a detailed description of any and all prior art upon which any claim of invalidity or unenforceability is based." *See* Ex. 1, at p. 22.

Cytac served its responses to TriPath's first set of interrogatories on December 10, 2003, but said nothing about the CDS-1000 in response to Interrogatory Number 6. Burke Decl., ¶3. On August 17, 2004, Cytac served its Objections and Supplemental Answers to Defendant's First Set of Interrogatories (Nos. 5 and 6), including a revised response to Interrogatory Number 6. Once again, Cytac said nothing regarding the CDS-1000 serving as an alleged basis for invalidity of any of the patents-in-suit. *Id.* Finally, at approximately 11 p.m. on January 31, 2005, Cytac faxed a service copy of its Second Set of Objections and Supplemental Answers to Defendant's First Set of Interrogatories (Nos. 5 and 6). In those second set of supplemental responses, Cytac disclosed for the first time an alleged invalidity theory against the '377 Patent based on its CDS-1000 project in response to Interrogatory Number 6:

184. The '377 patent claims are invalid in view of the CDS-1000, including the development and publication activities. The following documents are relevant to the development and publication of the CDS-1000 device: [omitted listing of documents]

Certain of the above references are also relevant to the issue of secondary considerations of obviousness of the invention claimed in the '377 Patent. Specifically, the CDS-1000 material, . . . are evidence that others had developed the subject matter of the invention prior to, and contemporaneous with, the inventors of the '377 patent.

See Ex. 1, at p.53-54.

Similarly, in the second set of supplemental responses, Cytyc disclosed for the first time an alleged invalidity theory against the '327 Patent based on its CDS-1000 project in response to Interrogatory Number 6:

The '327 patent claims are invalid in view of the CDS-1000, including the development and publication activities. The CDS-1000 was presented at industry trade shows in October 1990 and November 1991. The following documents are relevant to the development and publication of the CDS-1000 device: [omitted list of documents].

Certain of the above references are also relevant to the issue of secondary considerations of obviousness of the invention claimed in the '327 Patent. Specifically, the CDS-1000 material, . . . are evidence that others had developed the subject matter of the invention prior to, and contemporaneous with, the inventors of the '327 patent.

See id., at p.78.

Cytyc's interrogatory responses list a number of CDS-1000 documents as support for the stated positions. *See id.*, at pp. 53-54, 78. Cytyc produced these documents to TriPath during the discovery period on the dates indicated in the following chart:

CDS-1000 Documents		Production Dates
1	C0065268-90	March 12, 2004
2	C0074813-15	March 12, 2004
3	C0075231-33	March 12, 2004
4	C0075236-38	March 12, 2004
5	C0076406-39	March 12, 2004
6	C0076629-40	March 12, 2004
7	C0076911-12	March 12, 2004
8	C0081467-517	March 12, 2004
9	C0081554-88	March 12, 2004
10	C0082345-50	March 12, 2004
11	C0082366-68	March 12, 2004
12	C0082369-77	March 12, 2004
13	C0082422-26	March 12, 2004
14	C0083049-124	March 12, 2004
15	C0083299-305	March 12, 2004
16	C0083306-9	March 12, 2004
17	C0083312-15	March 12, 2004
18	C0083320-21	March 12, 2004

19	C0083327-29	March 12, 2004
20	C0083354-7	March 12, 2004
21	C0083370-73	March 12, 2004
22	C0083406-8	March 12, 2004
23	C0083420-30	March 12, 2004
24	C0083475-76	March 12, 2004
25	C0083580-90	March 12, 2004
26	C0083680-93	March 12, 2004
27	C0083772-84	March 12, 2004
28	C0083800-10	March 12, 2004
29	C0083861-64	March 12, 2004
30	C0083896	March 12, 2004
31	C0089612-17	March 12, 2004
32	C0093989-4071	March 15, 2004
33	C0094321-24	March 15, 2004
34	C0103018-63	April 23, 2004
35	C0103064-3215	April 23, 2004
36	C0139750-67	January 10, 2005
37	C0139768-85	January 10, 2005
38	C0139786-95	January 10, 2005
39	C0139796-809	January 10, 2005
40	C0139810-21	January 10, 2005
41	C0139822-28	January 10, 2005
42	C0139829-40	January 10, 2005
43	C0139841-50	January 10, 2005
44	C0139851-56	January 10, 2005
45	C0139857-91	January 10, 2005
46	C0139989-93	January 10, 2005
47	C0141289-467	January 20, 2005

See Ex. 11, letters accompanying Cytac productions. In addition, Cytac produced computer disks relating to the CDS-1000 on January 11, 21 and 27, 2005. *See* Ex. 9, letters from Amy Brooks.

Cytac's expert witnesses have relied upon the CDS-1000 in their expert reports regarding the alleged invalidity of the '377 and '327 patents. *See* Ex. 2, Expert Report of Dr. Trevor Jackson Darrell, at pp. 9, 10, 12, 18-20, 25-30, 33-35, 42; Ex. 3, Expert Report of Dr. Kenneth Castleman at pp. 26, 89-93. Moreover, Cytac's experts apparently did a significant degree of fact investigation regarding the CDS-1000 (an opportunity that TriPath never had). For example, Cytac's expert

witnesses interviewed David Zahniser for details about how the system worked and the purported time frames in which various aspects of development took place. *See* Ex. 3, at p. 91-92. Accordingly, Cytyc's experts intend to provide testimony in this case regarding the CDS-1000 serving as an allegedly invalidating piece of prior art, and Cytyc's fact witnesses also apparently plan to provide testimony to support the expert's conclusions.

III. ARGUMENT

A. Failure To Supplement Interrogatory Responses Results In Exclusion

Rule 26(e)(2) of the Federal Rules of Civil Procedure imposes a duty of supplementation upon a party's discovery responses. Rule 26(e) provides, in pertinent part, as follows:

A party who has . . . responded to a request for discovery with a disclosure or response is under a duty to supplement or correct the disclosure or response to include information thereafter acquired if ordered by the court or in the following circumstances:

(2) A party is under a duty to seasonably to amend a prior response to an interrogatory, request for production, or request for admission if the party learns that the response is in some material respect incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.

Fed. R. Civ. P. 26(e)(2).

Rule 37(c)(1) sets forth the remedy of exclusion for a party's failure to supplement its discovery responses:

A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), *or to amend a prior response to discovery as required by Rule 26(e)(2)*, is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed. In addition to or in lieu of this sanction, the court, on motion and after affording an opportunity to be heard, may impose other appropriate sanctions. In addition to requiring payment of reasonable expenses, including attorney's fees, caused by the failure, these sanctions may include any of the actions authorized under Rule 37(b)(2)(A), (B), and (C) and may include informing the jury of the failure to make the disclosure.

Fed. R. Civ. P. 37(c)(1) (emphasis added).

The First Circuit has explained that the 1993 Amendment to Rule 37(c)(1) “gave teeth to a significantly broadened duty to supplement” under Rule 26 of the Federal Rules.¹ *Wilson v. Bradlees of New England, Inc.*, 250 F.3d 10, 19 (1st Cir. 2001). Thus, “the new rule clearly contemplates stricter adherence to discovery requirements, and harsher sanctions for breaches of this rule, and *the required sanction in the ordinary case is mandatory exclusion.*”² *Klonoski v. Mahlab*, 156 F.3d 255, 269 (1st Cir. 1998), *cert. denied*, *Mary Hitchcock Mem. Hosp. v. Klonoski*, 526 U.S. 1039, 119 S. Ct. 1334 (1999) (emphasis added).

The directives of Rule 37(c)(1) are “mandatory” and impose a “self-executing” sanction. *See Poulis-Minott v. Smith*, 388 F.3d 354, 358 (1st Cir. 2004); *Wilson*, 250 F.3d at 21; *Klonoski*, 156 F.3d at 269; *see also* Advisory Committee Notes to 1993 Amendments (“The revision provides a self-executing sanction for a failure to make a disclosure required by Rule 26(a), without need for a motion . . .”). Rule 37(c)(1) “requires the near automatic exclusion of Rule 26 information that is not timely disclosed.” *Wilson*, 250 F.3d at 21. In particular, Rule 37(c)(1) provides for exclusion of the undisclosed information unless the party facing exclusion shows that it was “substantially justified” in its failure to disclose, or the failure to disclose was “harmless.” *See* Fed. R. Civ. P. 37(c)(1); *American Stock Exchange, LLC v. Mopex, Inc.*, 215 F.R.D. 87, 93 (S.D.N.Y. 2002). Therefore, the party opposing exclusion carries the burden of proof under Rule 37(c)(1): “it is the obligation of the party facing sanctions for belated disclosure to show that its failure to comply with

¹ “Rule 37(c)(1) was further amended in 2000 to make clear that a party’s failure to comply with the supplementation duty imposed by Rule 26(e)(2) was also sanctionable.” *Wilson v. Bradlees of New England, Inc.*, 250 F.3d 10, 19 n.18 (1st Cir. 2001).

² Accordingly, in view of the purposes underlying the amended Rule 37(c)(1), the First Circuit has instructed that “pre-1993 cases analyzing the sanction issue under the pre-amendment rubric retain only limited authority in this post-amendment era.” *Klonoski v. Mahlab*, 156 F.3d 255, 269 n.5 (1st Cir. 1998). The First Circuit’s reasoning applies with equal force to any pre-2000 cases (when Rule 37(c)(1) was amended to include Rule 26(e)(2)) analyzing the sanction issue for a failure to supplement discovery responses.

the Rule was either justified or harmless and therefore deserving of some lesser sanction.” *Wilson*, 250 F.3d at 21.

Accordingly, in view of the strict requirements of Rules 26(e)(2) and 37(c)(1), the federal courts in patent cases have routinely and consistently excluded all evidence relating to a theory of defense or liability that a party failed to disclose in supplemental interrogatory responses during the fact discovery period of the case.³ See, e.g., *Inamed Corp. v. Kuzmak*, 275 F. Supp.2d 1100, 1117-18 (S.D. Cal. 2002), *aff'd*, 2003 WL 21130011 (Fed. Cir. 2003) (entering preclusion sanction pursuant to Rule 37(c)(1) where defendant failed to disclose defense theory of a lack of authority to enter into settlement agreement in supplemental interrogatory responses); *American Stock Exchange*, 215 F.R.D. at 93-96 (granting motion to preclude evidence relating to plaintiff’s assertion of an additional patent claim covering substantially different subject matter that was not disclosed in supplemental interrogatory responses during the fact discovery period); *E-Z Dock, Inc. v. Schafer Systems, Inc.*, 2003 WL 1610781 *13-14 (D. Minn. 2003) (failure to timely disclose prior art reference in supplemental interrogatory responses warranted exclusion of the reference); *Thermos Co. v. Starbucks Corp.*, 1999 WL 203822 *3-7 (N.D. Ill. 1999) (granting motion to exclude all evidence relating to a non-infringement defense because defendant failed to supplement interrogatories and disclose that defense during fact discovery, and instead disclosed new non-infringement theory for first time in expert reports); *Heidelberg Harris, Inc. v. Mitsubishi Heavy Industries, Ltd.*, 1996 WL 680243 *7-9 (N.D. Ill. 1996) (defendants precluded from introducing any evidence relating to a section 112 “best mode” defense to patent infringement claim where they failed to supplement interrogatories and disclose theory during fact discovery, and instead disclosed defense theory for the first time in expert reports).

³ All cases cited herein that are not reported in West’s federal reporter system are attached as Exs. 12, 13 and 14 hereto.

As will be shown below, Cytyc's failure to supplement its interrogatory responses in this case likewise warrants exclusion of defenses relating to the CDS-1000.

B. Cytyc Cannot Show That Its Failure To Disclose Was Substantially Justified.

Cytyc cannot demonstrate that its failure to disclose a theory of invalidity until late on the last night of fact discovery is substantially justified. "Substantial justification means 'justification to a degree that could satisfy a reasonable person that parties could differ as to whether the party was required to comply with the disclosure request.'" *American Stock Exchange*, 215 F.R.D. at 93; *see also Nguyen v. IBP, Inc.*, 162 F.R.D. 675, 680 (D. Kan. 1995) (setting forth same legal standard for "substantial justification"). Here, there is no justification for Cytyc's failure to disclose an entirely new theory of invalidity during a lengthy fifteen-month fact discovery period (which was twice extended), let alone a "substantial" justification for such dilatory conduct.

First, Cytyc itself has recognized that its conduct is not substantially justified. *See* Ex. 6, letter dated March 16, 2005. In particular, the parties agree on the standard for determining whether or not a patent claim or defense was sufficiently disclosed in fact discovery. Indeed, on March 16, 2005, counsel for Cytyc wrote to TriPath to demand that TriPath withdraw one of its infringement claims (a claim for infringement of Claim 19 of the '377 Patent) that had not been disclosed in interrogatory responses during fact discovery. In support of demanding withdrawal of the claim, Cytyc's counsel stated the legal standard as follows:

The rules preclude [a party] from asserting -- after the close of fact discovery -- claims that were not disclosed in its answers to interrogatories. See, e.g., Fed. R. Civ. P. 26(e).

Id. The grounds for exclusion of undisclosed claims or defenses is particularly strong, according to Cytyc's counsel, when the documents relied upon to establish the undisclosed claim or defense were known from the early stages of the case but were not disclosed in interrogatories. Specifically, Cytyc complained that TriPath's expert reports included a claim for infringement of Claim 19 of the '377

Patent hat was not disclosed in interrogatory responses and that was based upon documents that were available early in the discovery period. *Id.* TriPath agreed that it made a mistake by failing to timely disclosed this infringement claim in its interrogatory responses and therefore TriPath voluntarily agreed to withdraw the disputed claim. *Id.*, letter dated March 23, 2005.

Cytec has made the exact same mistake by failing to timely disclose its invalidity defense based upon the CDS-1000, a defense that is based upon Cytec's own product and that was known to Cytec throughout the discovery period. TriPath would be at a tremendous disadvantage if Cytec were allowed to proceed with an invalidity argument based upon the CDS-1000 since TriPath had no notice of the claim during the fact discovery period, and TriPath therefore did not conduct any fact discovery regarding the claim. *See Ray Decl.*, ¶¶4-7; *Burke Decl.*, ¶¶3-4. Under these circumstances, the only feasible option is the same one that Cytec previously demanded of TriPath -- the undisclosed defense must be withdrawn (or excluded) and cannot be pursued in any proceedings in this case, including trial.

Second, the unjustified nature of Cytec's conduct is even further evident given the compelling evidence that Cytec was aware of the CDS-1000 prior art defense long before the defense was disclosed to TriPath. Since Cytec filed its declaratory judgment case in June, 2003, Cytec was certainly aware of its CDS-1000 product. Cytec's agents designed the product and knew all of the documents and design details that Cytec's experts are now relying upon to support the claim that the CDS-1000 invalidates two of TriPath's patents. Nevertheless, more than a year and a half later, Cytec still had not disclosed its CDS-1000 during fact discovery as an alleged basis for invalidity. At a minimum, Cytec knew in the Spring of 2004 that it would rely upon the CDS-1000 to try and invalidate TriPath's patents. Indeed, in the spring of 2004, some ten months before actual disclosure of its theory of invalidity, Cytec produced some documents relating to the CDS-1000. In fact, these are documents now being relied upon by Cytec's as supporting a basis for alleged invalidity. *See*

Exhibits 1, 2 and 3.⁴ Finally, the evidence proves that Cytyc tried to “set-up” TriPath with a final wave of CDS-1000 documents nearly ten months after the first part of the production – dumping them on TriPath at the end of the fact discovery period and just prior to the continued depositions of David Zahniser and Kam Lin Wong (two former employees involved in Cytyc’s CDS-1000 development efforts). Cytyc offered to postpone Dr. Zahniser’s deposition to allow TriPath time to produce the newly revealed software code for the CDS-1000.⁵ *See* Ex. 8, January 10, 2005 letter. Nevertheless, even at this stage of the proceedings, with relevant depositions remaining, Cytyc still refused to disclose its invalidity theory to TriPath. This failure to disclose is particularly egregious since Cytyc’s experts are relying heavily on the documents tardily produced by Cytyc in January, 2005. *See, e.g.*, Ex. 3, Castleman Report, at 89-93; Ex. 2, Darrell Report at 18-20.

Accordingly, Cytyc failed to supplement interrogatory responses with its invalidity theory for more than a year. Even though Cytyc was fully aware of its CDS-1000 and documents relating thereto (which are now being relied upon by its experts as a basis for invalidity), Cytyc engaged in a deliberate litigation strategy to keep this theory from TriPath until after the close of fact discovery so that TriPath could not conduct discovery on the pertinent issues. The purposes underlying Rules 26(e) and 37(c) are to avoid “surprise” and “trial by ambush.” *See American Stock Exchange*, 215 F.R.D. at 93. However, this is precisely the ambush litigation tactics employed by Cytyc in this case. Accordingly, Cytyc’s position is not substantially justified and preclusion of all defenses based on Cytyc’s CDS-1000 is warranted.⁶

⁴ Because Cytyc had not disclosed its prior art defense, TriPath assumed that the CDS-1000 documents concerned only infringement issues. This assumption was entirely reasonable since the CDS-1000 was the predecessor to the device accused of infringement. Ray Decl., ¶ 4.

⁵ Even after that, Cytyc continued to produce updated and different versions of the CDS-1000 software code. *See* Ex. 9, letters dated January 11, 21 and 27, 2005 from Amy Brooks to Charles Burke.

⁶ Cytyc has not claimed that its conduct was justified by 35 U.S.C. § 282. *See* Ex. 7 hereto, letter dated April 1, 2005. Nevertheless, sometimes defendants have made the specious argument that their dilatory conduct in providing prior art defenses was somehow justified by 35 U.S.C. § 282. Section 282 provides, among other things, that a

C. Cytac's Failure To Disclose Has Resulted In Severe Prejudice To TriPath.

Cytac cannot demonstrate that its failure to timely disclose a new theory of invalidity was harmless. "Failure to comply with the mandate of the Rule is harmless when there is no prejudice to the party entitled to the disclosure." *American Stock Exchange*, 215 F.R.D. at 93 (quoting *Nguyen*, 162 F.R.D. at 680)). Since TriPath has been prejudiced because of Cytac's failure to timely supplement its interrogatory responses, Cytac's failure to disclose was plainly not harmless in this case.

TriPath has been prejudiced in this case by being wholly deprived the opportunity to pursue needed fact discovery regarding the CDS-1000. *See, e.g., American Stock Exchange*, 215 F.R.D. at 95 (concluding that prejudice to AMEX included being "deprived of the opportunity to pursue needed fact discovery"); *Heidelberg Harris*, 1996 WL 680243 at *8 ("If a party is allowed to withhold the supplementation until after discovery is closed, the purpose of [Rule 26] is effectively frustrated because the opposing party is denied the opportunity to conduct discovery on the supplemented responses."). In this case, TriPath undertook no discovery regarding the alleged role of the CDS-1000 as invalidating prior art. *See Ray Decl.*, ¶¶ 4-7; *Burke Decl.*, ¶4. Rather, TriPath understood the CDS-1000 simply to be internal development efforts that resulted in a failed product development (in 1994), but that may have been used in some respects as a starting point for

party asserting invalidity shall give notice "at least thirty days before the trial, of the country, number, date, and name of" any patent or publication to be relied upon in anticipation of the patent-in-suit. The Federal Circuit has made clear that, while Section 282 sets a minimum period for identification of certain prior art, "when the court has set and the parties have agreed to a discovery period, that procedure necessarily governs that trial" and "a specific judicial directive for the timing of discovery establishes the procedures to which the parties are bound." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 535, 551 (Fed. Cir. 1998) (excluding prior art because defendant presented no reason to justify inclusion of prior art that was presented four months after extended discovery ended). Thus, Rules 26(e)(2) and 37(c)(1) alone determine whether a failure to supplement discovery responses warrant exclusion of the prior art. *See, e.g., Abbott Laboratories v. Syntron Bioresearch, Inc.*, 2001 WL 34082555 *2-3 (S.D. Cal. 2001) (upholding Magistrate Judge's exclusion of nine prior art references); *E-Z Dock, Inc.*, 2003 WL 1610781 at *13-14 (failure to timely disclose prior art reference in supplemental interrogatory responses warranted exclusion of the reference). Thus, section 282 has no application to this motion.

development in 1997 of the infringing ThinPrep Imaging System. *Id.* Thus, TriPath was unable to take the necessary depositions and other fact discovery necessary on the CDS-1000.

Fact discovery was essential to preparation of TriPath's case because Cytyc is making claims regarding the CDS-1000 that (i) are not included in the documents themselves, (ii) contradict the documents as well as prior deposition testimony in the case, and (iii) that are factually detailed based on how the CDS-1000 purportedly worked at various points in time. For example, Cytyc's expert makes clear that because many of the CDS-1000 documents have been destroyed, he is relying upon oral testimony being provided by Cytyc's witnesses. *See* Ex. 3, Castleman Report, at. p. 91. In addition, Cytyc's experts will be relying upon witnesses to establish that the CDS-1000 was publicly disclosed in some form at various trade shows. *See* Exs. 2 and 3, Castleman Report, at. p. 90 and Darrell Report, at p. 18; Ex. 1, Cytyc's Supplemental Interrogatories, at pp. 53-54, 78. TriPath is prejudiced by not being allowed to challenge this oral testimony through discovery and, in particular, not being able to challenge through extensive fact discovery the purported embodiments of the CDS-1000 that existed over the course of 6 years and that allegedly may have been disclosed at various times to the public (e.g., Cytyc's claim that device constitutes "prior art" to the two patents-in-suit).

TriPath is also prejudiced because Cytyc is now claiming that, from early on in development, the CDS-1000 was a form of "semi-automated" prior art. This is an important issue because two of the patents-in-suit concern a semi-automated device, and the CDS-1000 could be invalidating only if (among many other things) it was also a semi-automated device. However, because Cytyc never disclosed the CDS-1000 as prior art while there was any time remaining in the discovery period, and because TriPath understood from other sources that the CDS-1000 was a fully automated device,⁷

⁷ In its 1996 NIH grant proposal, Cytyc states that it "will develop and test a complete prototype of an automated cervical analysis system for use after manual screening as a Quality Control (QC) instrument." Ex. 5. In addition, Mr. Geiselman, Cytyc's head of engineering, testified that he believed the CDS-1000 was fully automated in that it made a diagnosis, where as he was of the opinion that a more appropriate market approach for development of the accused ThinPrep Imaging System would be semi-automation. *See* Ex. 4, Geiselman transcript, at pp. 39-44.

TriPath never knew that it needed to explore the issue. Only if Cytec had disclosed the CDS-1000 as prior art could TriPath have known that it needed to fully explore this issue.

TriPath's prejudice also stems from its failure to learn of Cytec's theory of invalidity because such a theory necessitates detailed factual discovery as to what the CDS-1000 was in terms of structure and function, how it accomplished those functions and how the design of the product changed over time. Indeed, the complexity of these issues are evident by the fact that Cytec's development of this product spanned more than 6 years, some of these events took place more than 15 years ago, and Cytec's own experts are having to rely on witness testimony to purportedly fill in the gaps in the documents themselves. *See* Ex. 3, at pp. 91-92

Finally, TriPath has been prejudiced because its experts were forced to hurriedly respond to Cytec's allegations regarding the CDS-1000 as invalidating art without the benefit of fact discovery. Indeed, TriPath's experts noted in their reports the comparative disadvantage because Cytec's experts were able to conduct fact investigations regarding the CDS-1000 such as interviews of Cytec witnesses, and TriPath's experts had no access to similar information.⁸ *See American Stock Exchange*, 215 F.R.D. at 95 (concluding that prejudice included that the AMEX was "compelled to have its expert assess the issue at the last minute without the benefit of fact discovery."); *Inamed Corp.*, 275 F. Supp.2d at 1119 (prejudice included having to "digest Hunt's deposition hurriedly and to respond to the argument only in reply to summary judgment motion"). Thus, TriPath has been prejudiced because its experts had to quickly review a large volume of CDS-1000 materials and did

⁸ For example, Dr. Peter H. Bartels stated in his expert report regarding the validity of the '327 patent (at p. 42):

Although I have concluded that the CDS-1000 is not a piece of prior art that invalidates the '327 patent, there is a significant volume of information regarding the CDS-1000 that I would like to have in order to more completely analyze the opinions of Dr. Darrell regarding this device but that is not available. For example, although I have read the depositions of technical witnesses in this case, there was no testimony provided regarding CDS-1000 documents upon which Dr. Darrell relies in his report. I also do not have any details regarding the conversations with David Zahniser regarding the CDS-1000 upon which Dr. Darrell bases many of his conclusions. I reserve the right to supplement this report and the opinions expressed herein should additional information regarding the CDS-1000 become available.

not have complete factual information in order to base their opinions regarding these materials. It is unfair and prejudicial that Cytac's experts would be able to have access to more complete factual information regarding the allegedly invalidating product via oral communications with Cytac's witnesses.

D. Cytac's Grounds Opposing Exclusion Are Without Merit.

Cytac has claimed in a letter to TriPath, and presumably will make the same arguments to this Court, that exclusion of evidence relating to the CDS-1000 is not warranted because (i) TriPath supplemented its own interrogatory responses on the final day of discovery; (ii) TriPath had opportunity to take discovery regarding the CDS-1000, and (iii) TriPath added patent claims to this case in January, 2005. *See* Ex. 7, letter dated April 1, 2005. Each of Cytac's positions is without merit and fails to demonstrate any substantial justification for Cytac's conduct or the lack of prejudice to TriPath from Cytac's failure to disclose.

In the first place, Cytac is certainly well aware that it cannot justify its own misconduct by pointing to conduct undertaken by another party in the case. Nevertheless, this is precisely what Cytac does by claiming that its position is justified because TriPath supplemented certain interrogatories on the last day of discovery. Moreover, Cytac's position conveniently ignores three key facts. First, TriPath's supplementation did not disclose any new claims for liability. Instead, TriPath simply supplemented with more detailed information regarding conception and reduction to practice. This is in sharp contrast to Cytac's supplementation which included identification of entire new defenses (invalidity based upon the CDS-1000) that was never previously disclosed. Second, when TriPath's expert reports included a new infringement claim, Cytac was quick to point out that it was improper to disclose new theories after the close of fact discovery. *See* Ex. 6. TriPath did the right thing and withdrew the claim that had not been disclosed during fact discovery. *See id.* The result from Cytac's assertion of a previously undisclosed defense should be the same. Third, Cytac

conveniently ignores that TriPath supplemented its interrogatory responses not because there was a claim or evidence that it wanted to assert but had not disclosed, but instead only because Cytac had requested the supplementation and TriPath did so to try and avoid an unnecessary discovery dispute. *See* Ex. 10, letters from Cytac's counsel, Amr Aly. Thus, TriPath's supplementation is not a justification for Cytac's improper conduct.

Moreover, as explained previously, the mere fact that TriPath was aware of the CDS-1000 device based on documents produced by Cytac in no way meant that TriPath was aware, and conducted discovery, on the new invalidity theory alleged by Cytac after the close of fact discovery. To the contrary, TriPath had no knowledge of such a theory and took no fact discovery thereon. Thus, TriPath was plainly prejudiced by Cytac's conduct as previously described herein. *See* Ray Decl., ¶¶4-7 ; Burke Decl., ¶4.

In *Heidelberg Harris*, *supra*, 1996 WL 680243, the court rejected the same type of argument Cytac is attempting to make in this case – that TriPath had general notice of the CDS-1000 documents and thus was not prejudiced. In particular, the *Heidelberg Harris* court stated that:

While the Plaintiff was given general notice of Defendants' intent to assert a Section 112 defense, both through the Defendants' answer and its responses to interrogatories, the details of and the basis for that defense were never fleshed out until after fact discovery closed and the Defendants' expert reports were disclosed.

* * * *

The Court finds that, while the Defendants' answer and nebulous interrogatory responses may have served to put Harris on notice as to the possibility of a Section 112 defense being raised, they failed to apprise Harris of the substance and basis for that defense. Consequently, the Court finds that Harris was surprised as to the factual basis and substance of Defendants' 112 defense.

Heidelberg Harris, 1996 WL 680243 at *7, 8. Here, the case for exclusion is even more compelling than in *Heidelberg Harris* because Cytac never gave any notice in a pleading or interrogatory response, whether nebulous or not, regarding its reliance on the CDS-1000 as allegedly invalidating prior art.

Cytec's attorneys also suggest that they produced certain of the remaining CDS-1000 documents in January as soon as they were located. *See* Ex. 7. Of course, when certain documents may have been located is a different issue than when they should have been located and, more importantly, when Cytec should have disclosed its theory of invalidity which is based on the documents regarding the CDS-1000 product that had already been produced. In addition, the courts have rejected the notion that a party can be substantially justified in its tardiness based on a failure to locate existing company documents. *See Fritz v. American General Finance, Inc.*, 1999 WL 619045 * 6 (D. Kan. 1999) ("That outside counsel and an in-house paralegal did not know of the existence of the documents until shortly before disclosing them provides insufficient justification to excuse the untimely disclosures."). Thus, Cytec cannot attempt to justify its own tardy disclosures upon its own failure to diligently search for and locate company documents that were available from the inception of this case.

Finally, Cytec's passing reference to TriPath's assertion of two patent claims in supplemental interrogatory response in January 2005 has nothing to do with Cytec's conduct that is the subject of the is motion. Indeed, Cytec would not even be raising this issue except that it wants to deflect attention from its wrongful conduct. Further, Cytec fails to mention that the two claims asserted were only dependent claims (Claims 17 and 21), and related to the same subject matter as asserted Claim 16 of U.S. Patent No. 5,793,969 ("969 Patent"). Finally, Cytec fails to mention that it was fully aware of these claims when it took deposition of Bruno Krief (TriPath's employee and key developer of the system that Cytec alleges invalidates '969 Patent) and three of the co-inventors of the '969 Patent in February 2005. Thus, this issue is simply a red herring and if Cytec had any serious complaint about this issue it would have so indicated in the Joint Status Report filed with the Court on May 3, 2005.

IV. CONCLUSION

The First Circuit has instructed that “absent some unusual extenuating circumstances . . . the appropriate sanction when a party fails to provide certain evidence to the opposing party as required by the discovery rules is preclusion of that evidence from trial.” *Klonoski*, 156 F.3d at 271. No such extenuating circumstances exist in this case. Rather, Cytac undertook a deliberate litigation strategy to ambush TriPath with entirely new theories of invalidity after the close of fact discovery. Accordingly, for all of the foregoing reasons, TriPath respectfully requests that the Court grant its motion to exclude all defenses relating to the CDS-1000 from any proceedings in this case, including trial.

Respectfully submitted this the 5th day of May, 2005.

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